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Original Article

Comparing the outcomes of two strategies for colorectal tumor detection: Policy-promoted screening program versus health promotion service

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Abstract

Background: The Taiwanese government has proposed a population-based colorectal tumor detection program for the average-risk population. This study's objectives were to understand the outcomes of these screening policies and to evaluate the effectiveness of the program.
Methods: We compared two databases compiled in one medical center. The "policy-promoted cancer screening" (PPS) database was built on the basis of the policy of the Taiwan Bureau of National Health Insurance for cancer screening. The "health promotion service" (HPS) database was built to provide health check-ups for self-paid volunteers. Both the PPS and HPS databases employ the immunochemical fecal occult blood test (iFOBT) and colonoscopy for colorectal tumor screening using different strategies. A comparison of outcomes between the PPS and HPS included: (1) quality indicators—compliance rate, cecum reaching rate, and tumor detection rate; and (2) validity indicators—sensitivity, specificity, positive, and negative predictive values for detecting colorectal neoplasms.
Results: A total of 10,563 and 1481 individuals were enrolled in PPS and HPS, respectively. Among quality indicators, there was no statistically significant difference in the cecum reaching rate between PPS and HPS. The compliance rates were 56.1% for PPS and 91.8% for HPS ($p < 0.001$). The advanced adenoma detection rates of PPS and HPS were 1.0% and 3.6%, respectively ($p < 0.01$). The carcinoma detection rates were 0.3% and 0.4%, respectively ($p = 0.59$). For validity indicators, PPS provides only a positive predictive value for colorectal tumor detection. HPS provides additional validity indicators, including sensitivity, specificity, positive predictive value, and negative predictive value, for colorectal tumor screening.
Conclusion: In comparison with the outcomes of the HPS database, the screening efficacy of the PPS database is even for detecting colorectal carcinoma but is limited in detecting advanced adenoma. HPS may provide comprehensive validity indicators and will be helpful in adjusting current policies for improving screening performance.

Keywords: colorectal cancer; effectiveness; screening

1. Introduction

Colorectal cancer (CRC) accounts for the highest number of newly diagnosed cancer cases and is the third leading cause of cancer deaths in Taiwan.[1,2] Most CRC develops via the well-known adenoma–carcinoma sequence that averages 10–15 years for evolution.[3,4] The generally slow rate of progression provides the possibility for clinicians to reduce mortality and morbidity of CRC by detecting neoplasms in the precancerous or early stages through adequate screening for the average-risk population.[5] Currently, there are two main options for CRC screening in the average-risk population, stool tests and endoscopic exams. Growing evidence suggests applying these options

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in a systematic program of periodic screening has the potential to significantly reduce deaths from CRC.[6]

The Taiwan Bureau of National Health Insurance began population-based CRC detection programs in 2006 for people between the ages of 50 years and 69 years using the immunochemical fecal occult blood test (iFOBT) screening for detecting asymptomatic CRC.[7] This policy was extended to all medical centers in Taiwan and was modified to be a community–hospital collaboration model in 2010, but little is known about its effectiveness. In this report, we present our data evaluating the performance and outcomes of this public policy and discuss its prospects by comparing it with the current hospital-based health promotion service.

2. Methods

2.1. Comparable databases and strategies for colorectal tumor detection

We compared two databases compiled in one medical center. The "policy-promoted cancer screening program" (PPS) database was designed on the basis of the policies of the Taiwan Bureau of National Health Insurance for screening of four types of cancers highly prevalent in Taiwan, including oral cancer, breast cancer, cervical cancer, and CRC. Strategies for CRC detection in PPS are limited to average-risk individuals who are asymptomatic and between the ages of 50 years and 69 years. We applied the iFOBT (Kyowa, Tokyo, Japan or Eiken, Tokyo, Japan) screening for all participants in the PPS group. Colonoscopic examination was performed for people with positive iFOBT results. If a polyp was observed, polypectomy was applied to obtain histological results. The information available in CRC screening datasets of PPS include age, gender, health style, geographical data, screening tool, confirmed tool, and histological reports. The "health promotion service" (HPS) database was designed to provide health education, disease prevention, detection, and long-term follow-up for a variety of populations. The fields in the HPS database are more comprehensive and include age, gender, geographical, social, and medical records data. Similar to our previous report, strategies for detecting CRC in HPS were administered to a wide spectrum of participants who were volunteers from the community or employees of companies with self-paid health check-ups, and included a combination of iFOBT and colonoscopy examination.[8] Polypectomy was performed if adenoma was observed during colonoscopic examination.

2.2. Participants and definitions

We retrospectively analyzed data from the two databases from January to October 2010. To compare these databases, we filtered HPS data by age. Participants aged between 50 years and 69 years were enrolled in the analysis. A comparison of outcomes between the two strategies was divided into a quality dimension and a validity dimension. In the quality dimension, we calculated the compliance rate, cecum reaching rate, and tumor detection rate of colonoscopy for PPS and HPS. Incomplete examinations due to very poor colon preparation were excluded. Colonoscopic compliance rates of PPS and HPS were determined by number of colonoscopies/number of iFOBT positive stools and number of people undergoing both iFOBT and colonoscopy/number of people attending health check-ups, respectively. Cecal intubation rate was defined as the number of photographic documentations of the cecal landmark/number of colonoscopies). The tumor detection rate was calculated as the number of cases with tumors/the total number of participants. We classified colorectal tumor as a polyp, advanced adenoma, or carcinoma. A polyp was defined according to colonoscopic finding regardless of the size and histological characteristics. Advanced adenoma was defined by the presence of any of the following histological or gross findings: villous adenoma, high-grade dysplasia, and diameter of adenoma >1 cm.[9] Carcinoma was defined according to histological diagnosis. In the validity dimension, we evaluated the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of iFOBT to detect polyps, advanced adenoma, and carcinoma in the PPS and HPS by using per-protocol analysis and with the intention to treat the cancer. All statistical analyses were conducted using SAS software (SAS program for Windows, version 9.1.3; SAS institute Inc., Cary, NC, USA) to compare the two databases. The differences between groups were assessed by two-tailed Student t test and Chi-square test. A p value of <0.05 was considered to be statistically significant. The hospital ethics committee approved this study. The Institutional Review Board (IRB) number of this study was 95E-056.

3. Results

3.1. Demographic characteristics

A total of 10,563 asymptomatic individuals aged between 50 years and 69 years attended the PPS program between January and October 2010. There were 3106 individuals in the HPS group. After filtration by age, 1481 participants aged between 50 years and 69 years were enrolled for subsequent

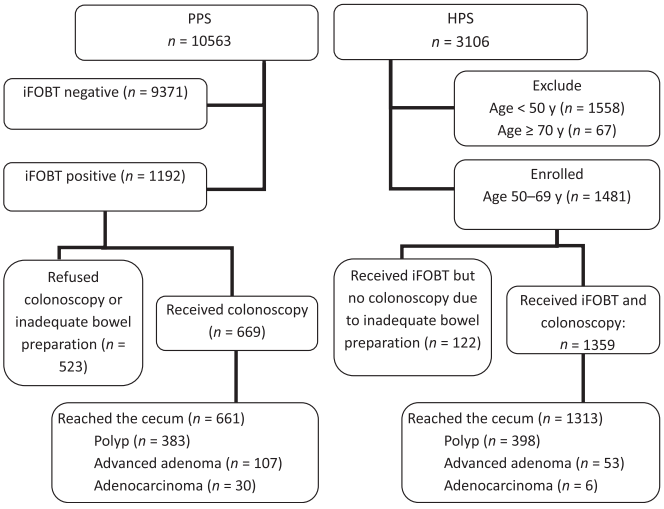

Fig. 1. Flowchart of study participants of PPS and HPS. HPS = health promotion service; iFOBT = immunochemical fecal occult blood test; PPS = policy-promoted screening.

analysis (Fig. 1). Demographic characteristics and basic measurements of the two groups, including age, gender, screening tool, and policy, are shown in Table 1.

3.2. Quality dimension

For the PPS group, the compliance rate of colonoscopy was 56.1% (669/1192). The cecal intubation rate was 98.8% (661/669). In all individuals willing to participate in the national CRC screening program, the tumor detection rates for polyp, advanced adenoma, and adenocarcinoma were 3.6% (383/10,563), 1.0% (107/10,563), and 0.3% (30/10,563), respectively. In the HPS group, the compliance rate was 91.8% (1359/1481), and the cecal intubation rate was 96.6% (1313/1359). Among the 1481 participants, the tumor detection rates for polyp, advanced adenoma, and adenocarcinoma were 26.9% (398/1481), 3.6% (53/1481), and 0.4% (6/1481), respectively. Differences between the PPS and HPS groups in these quality indicators are listed in Table 2.

3.3. Validity dimension

Due to limitations of the screening policy, we were only able to calculate the PPV of the PPS group by using the samples as per the screening protocol ($n = 669$). The PPV for polyps, advanced adenoma, and adenocarcinoma were 57.2% (383/669), 16.0% (107/669), and 4.5% (30/669), respectively. In the HPS group, both iFOBT and colonoscopy were provided to participants. We calculated the validity indicators for iFOBT in individuals who adhered to the protocol ($n = 1359$). The sensitivity, specificity, PPV, and NPV for detecting colorectal polyps were 22.5% (80/356), 90.2% (905/1003), 44.9% (80/178), and 76.6% (905/1181), respectively. The sensitivity, specificity, PPV, and NPV for detecting advanced adenoma were 45.7% (21/46), 88.0% (1156/1313), 11.8% (21/178), and 97.9% (1156/1181), respectively. The sensitivity, specificity, PPV, and NPV for detecting adenocarcinoma were 83.3% (5/6), 87.2% (1180/1353), 2.8% (5/178), and 99.9% (1180/1181), respectively. Differences in these validity indicators between the PPS and HPS are listed in Table 3.

4. Discussion

Several population-based studies suggest that screening of colorectal neoplasms using iFOBT can reduce mortality.

Table 2
Comparison of quality indicators between PPS and HPS.

	PPS ($n = 10,563$)	HPS ($n = 1481$)	p
Compliance rate of colonoscopy	56.1%	91.8%	<0.001
Cecum reaching rate of colonoscopy	98.9%	96.6%	NA[a]
Tumor detection rate for:			
Polyp	3.6%	26.9%	<0.001
Advanced adenoma	1.0%	3.6%	<0.001
Adenocarcinoma	0.3%	0.4%	0.59

HPS = health promotion service; iFOBT = immunochemical fecal occult blood test; PPS = policy-promoted screening.
[a] Both values are >95%, reflecting satisfactory quality.

Several countries have applied these results with some modification to strategies for CRC screening.[10–13] Despite its widespread use, little is known regarding the validity of iFOBT in colorectal neoplasia screening outcomes. In this study, we evaluated two databases in which the iFOBT was conducted for asymptomatic, average-risk individuals aged between 50 years and 69 years. These databases are independent and use different screening protocols. By comparing their outcomes, we can understand the benefits and limitations of these two strategies commonly used for detecting colorectal tumors.

Upon examining the quality dimensions of these two groups, some key indicators showed significant differences. The compliance rate for colonoscopy was 91.7% in the HPS group. The high compliance rate is primarily due to the one-step screening design—both iFOBT and colonoscopy are included in the examination set. In the PPS group, the compliance with colonoscopy in participants who were positive in the iFOBT was 56.1%. Increasing compliance with colonoscopy clearly enhanced screening performance and may have further reduced CRC mortality. Factors influencing compliance rates may include geographical remoteness,[14] educational attainment,[15] cleaning agents used for colonoscopy,[16] and the physician's alertness.[17,18] Additional effort should be made to improve public awareness on the benefits of adhering to screening protocols. The colorectal neoplasm detection rate is another important quality indicator for PPS and HPS. Our analysis revealed that participants in the HPS group exhibited a much higher polyp detection rate and advanced adenoma detection rate than those in the PPS group (26.9% vs. 3.6%, $p < 0.05$; and 3.5% vs. 1.0%, $p < 0.05$), but the difference in detecting carcinoma was not significant between the two groups (Table 2). These results reflect the differences in screening designs and

Table 1
Demographic characteristics and screening policies of PPS and HPS.

	PPS ($n = 10,563$)	HPS ($n = 1481$)	p
Aim	Single—detection of colorectal tumor	Multiple—including detection of colorectal tumor	NA
Population	Average-risk population from the community	Individual volunteers from the community or employees of companies	NA
Fee	National health insurance	Self-paid	NA
Strategy for colorectal tumor screening	Two-step (iFOBT(+) → colonoscopy)	One-step (combine iFOBT and colonoscopy)	NA
Positive rate of iFOBT	11.3%	12.0%	0.88
Age (y)	50–69 (mean: 58)	50–69 (mean: 57)	0.12
Gender (M:F)	49%:51%	55%:45%	0.40

HPS = health promotion service; iFOBT = immunochemical fecal occult blood test; PPS = policy-promoted screening.

Table 3
Comparison of validity indicators between PPS and HPS.

	Detection of polyp		Detection of advanced adenoma		Detection of adenocarcinoma	
	PPS ($n = 669$)	HPS ($n = 1359$)	PPS ($n = 669$)	HPS ($n = 1359$)	PPS ($n = 669$)	HPS ($n = 1359$)
Sensitivity	—	22.4%	—	45.6%	—	83.3%
Specificity	—	90.2%	—	88.0%	—	87.2%
PPV	57.2%*	44.9%	16.0%**	11.8%	4.5%***	2.8%
NPV	—	76.6%	—	97.9%	—	99.9%

*$p < 0.001$.
**$p = 0.48$.
***$p = 0.43$.
HPS = health promotion service; NPV = negative predictive value; PPS = policy-promoted screening; PPV = positive predictive value.

adherence to the PPS and HPS. Importantly, these results also suggested that current PPS strategies are not satisfactory for detecting advanced adenoma. Because most CRCs develop through the adenoma−carcinoma sequence,[3] setting a screening end point for detecting advanced adenoma is reasonable. The most effective method for improving the power of PPS for identifying advanced adenoma remains to be elucidated.

The validity dimension is very helpful for understanding the efficacy of the screening program. Similar to other population-based studies, PPS can only provide a PPV for iFOBT in detecting colorectal tumors.[12,19,20] The PPV of PPS in the screening of colorectal advanced adenoma and carcinoma are small, and many positive results may be false positives. Therefore, in the PPS group, we conducted colonoscopy for iFOBT(+) participants. However, PPS was not able to make suggestions for those with iFOBT(−) or poor compliance (Table 3). Taking the advantage of the design of HPS, we can easily calculate other key validity indicators, including the sensitivity, specificity, PPV, and NPV, of iFOBT in detecting colorectal neoplasms (Table 3). As false negative results may affect the performance of the screening program, these results can provide a valuable estimate of the false negative results in PPS. Additionally, these estimations may contribute to the understanding of limitations in population-based screening and may indicate reliable suggestions for individuals testing negative.

Our study has several limitations. Firstly, a population bias may exist even with adjustment for age. Compared with PPS, participants in the HPS group may have a higher socioeconomic status, pay more attention to their health, and may enjoy a better lifestyle; therefore, the incidence of colorectal neoplasms may be different. Secondly, the number of individuals in the HPS group was small, and therefore, the power of the study is limited. Thirdly, we did not perform a cost-effectiveness analysis.

In conclusion, compared with the outcomes of the HPS, the screening efficacy of the PPS is similar in detecting colorectal carcinoma, but is limited in detecting advanced adenoma. Additionally, HPS may provide a greater number of validity indicators and can be applied to modify current national screening strategies for improving screening performance.

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